IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

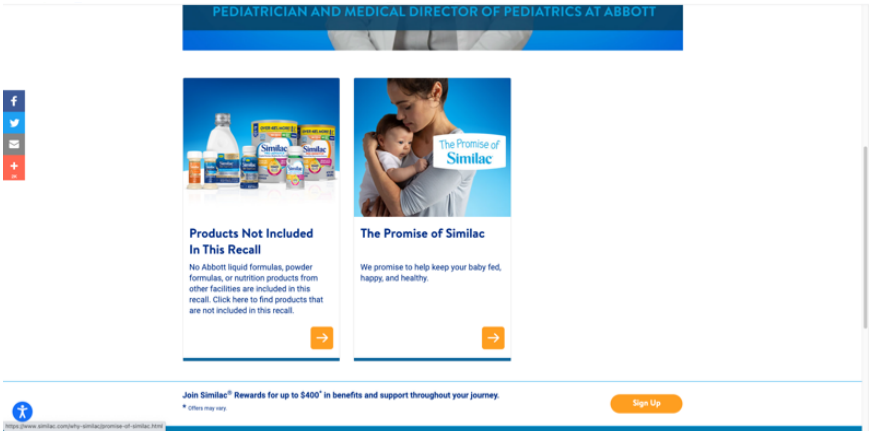
HEATHER DAVIS individually and as the legal guardian of a minor child, T.D. Plaintiff, v. ABBOTT LABORATORIES INC., Defendant.	Case NO.: 1:22-cv-5558 **COMPLAINT AND DEMAND** **FOR JURY TRIAL**

COMPLAINT

Plaintiff Heather Davis, individually and as the legal guardian of a minor child, T.D., on personal knowledge with respect to facts pertaining to them and upon information and belief as to other matters, brings this complaint against Defendant, ABBOTT LABORATORIES INC ("Defendant" or "ALI"), and allege:

INTRODUCTION

1. Plaintiff brings this action to redress Defendant's numerous unfair and deceptive acts and practices designed to mislead the public in connection with their promotion, marketing, advertising, packaging, labeling, distribution and/or sale of Similac Infant Formula, including but not limited to Similac®, Alimentum® and EleCare® products ("said Similac products") which Defendants unfairly and deceptively promoted during the relevant time period as containing ingredients safe for infant consumption and being safe for use, when, in fact, they cause bacterial infections and gastrointestinal illnesses such as Cronobacter Sakazakii, Salmonella, diarrhea, gastrointestinal illnesses, and other serious health problems.



https://www.similac.com/home.html

2. Similac, owned and made by ABBOTT LABORATORIES INC., tells consumers that "[t]he Promise of Similac… [is] to help keep your baby fed, happy, and healthy"[1] and that Similac brand is "Nutrition you can trust."[2] But recent testing at one of Abbott Nutrition's manufacturing facilities tells a different story – one of broken promises, mistrust and concealment. After receiving consumer complaints of *Cronobacter sakazakii* and *Salmonella* infections, the FDA's investigation along with the U.S. Centers for Disease Control and Prevention, and state and local partners, confirmed that Abbott Nutrition's Sturgis, Michigan facility had findings to date of "several positive *Cronobacter sakazakii* results from environmental samples taken by the FDA and adverse inspectional observations by the FDA investigators."[3]

3. Moreover, Politico reported that the FDA first received a report of a foodborne illness suspected to be linked to infant formula in September – four months before issuing the recall of three major brands – after four babies were hospitalized and one died.[4] The Minnesota Department of Health investigated a case of an infant who was sickened by *Cronobacter sakazakii* in September 2021, the state agency told Politico.[5] State health officials in Minnesota knew that the infant had

[1] *Similac Home,* Abbott, 2022, https://www.similac.com/home.html (last visited Feb. 22, 2022).
[2] *The Promise of Similac,* Abbott, 2022 https://www.similac.com/why-similac/promise-of-similac.html (last visited Feb. 22, 2022).
[3] *FDA News Release*, Feb. 17, 2022, https://www.fda.gov/news-events/press-announcements/fda-warns-consumers- not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility (last visited Feb. 20, 2022).
[4] FDA learned of suspected infant formula illness four months before recall, February 18, 2022, https://www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226 (last visited Feb. 22, 2022)
[5] *Id.*

consumed powdered formula produced at an Abbott Nutrition facility in Sturgis, Mich., and shared this information with the FDA and CDC in September of 2021.[6] Inspectors found Cronobacter sakazakii in several environmental samples taken at the plant, *as well as records suggesting the company had been finding the bacteria in the plant and had destroyed product because of the issue.*[7]

JURISDICTION & VENUE

4. Plaintiff is a citizen of Trenton, Florida.

5. Defendant, Abbott Laboratories Inc is a Delaware corporation with a principal place of business in Abbott Park, Lake County, Illinois.

6. Defendant transacts business within this District through sale of infant formula within this District, at grocery stores, drug stores, big box stores, membership stores, and online, sold directly to the citizens of this District.

7. This Court has personal jurisdiction over Defendant because they have substantial aggregate contacts with this District, including engaging in conduct in this District that has a direct, substantial, reasonably foreseeable, and intended effect of causing injury to persons throughout the United States, and because they purposely availed themselves of the laws of the United States and Illinois, including in this District, and/or has caused its products to be disseminated in this District.

8. Venue is proper in this district pursuant to to 28 U.S.C. §1391 because Defendant is subject to personal jurisdiction in this district and regularly conducts business in this district.

FACTUAL ALLEGATIONS

9. Plaintiff repeats, reiterates, and realleges, each and every allegation contained in this complaint with the same force and effect as if fully set forth herein.

10. Abbott Laboratories Inc., ("Defendant") manufactures, labels, markets, and sells infant formula under the Similac, Alimentum, and Elecare brands.

[6] *Id.*
[7] *Id.*

11. On February 17, 2022, the U.S. Food and Drug Administration ("FDA") announced it was investigating consumer complaints of Cronobacter and Salmonella infections related to ingestion of Similac, Alimentum and EleCare.

12. Specifically, the FDA announced it was: "investigating consumer complaints of Cronobacter *sakazakii* and Salmonella Newport infections. All of the cases are reported to have consumed powdered infant formula produced from Abbott Nutrition's Sturgis, Michigan facility. As a result of the ongoing investigation, along with the U.S. Centers for Disease Control and Prevention and state and local partners, the FDA is alerting consumers to avoid purchasing or using certain powdered infant formula products produced at this facility. This is an ongoing investigation, and the firm is working with the FDA to initiate a voluntary recall of the potentially affected product."[8]

13. The FDA news release further advised consumers should "not use Similac, Alimentum, or EleCare powdered infant formulas if:

- the first two digits of the code are 22 through 37; and
- the code on the container contains K8, SH or Z2; and
- the expiration date is 4-1-2022 (APR 2022) or later.*"*[9]

14. The FDA news release also advised it was "investigating complaints of four infant illnesses from three states. All four cases related to these complaints were hospitalized and *Cronobacter* may have contributed to a death in one case. The FDA has initiated an onsite inspection at the facility. Findings to date include several positive *Cronobacter sakazakii* results from environmental samples taken by the FDA and adverse inspectional observations by the FDA investigators. A review of the firm's internal records also indicates environmental contamination with *Cronobacter sakazakii* and the firm's destruction of product due to the presence of *Cronobacter*."[10].

[8] News Release, Food & Drug Administration, FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan (Feb. 17, 2022), https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use- certain-powdered-infant-formula-produced-abbott-nutritions-facility.
[9] *Id.*
[10] *Id.*

15. The FDA Deputy Commissioner for Food Policy and Response, Frank Yiannas, expressed concern over the infant food contamination noting "As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections."[11].

16. Cronobacter bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine). Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths and abnormal movements. Cronobacter infection may also cause bowel damage and may spread through the blood to other parts of the body.[12] Further, according to the CDC, Cronobacter infections can result in the death of babies.[13]

17. Salmonella are a group of bacteria that can cause gastrointestinal illness and fever called salmonellosis. Most people with salmonellosis develop diarrhea, fever and abdominal cramps. More severe cases of salmonellosis may include a high fever, aches, headaches, lethargy, a rash, blood in the urine or stool, and in some cases, may become fatal.[14]

18. On or about November, 2021, Plaintiff purchased Similac for her infant child.

19. At least one of the infant formula containers purchased had lot numbers matching the tainted lots identified by the FDA news advisory (33730SHO with a use by date of April 1, 2024).

20. Plaintiff's minor child, T.D., consumed the tainted infant formula.

21. On or about February of 2022, Plaintiff T.D. began developing symptoms of gastro intestinal distress including: overwhelming diarrhea; feverish temperatures; dehydration; sleeplessness; and other pain and injuries.

22. On November 24, 2021, Plaintiff T.D. was diagnosed with Salmonella.

23. Plaintiff T.D.'s illness was caused by the consumption of the tainted Similac.

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[11] *Id.*
[12] *Id.*
[13] *CDC Cronobacter*, 2022, https://www.cdc.gov/cronobacter/index.html (last visited on February 22, 2022)
[14] *FDA News Release*, Feb. 17, 2022, https://www.fda.gov/news-events/press-announcements/fda-warns-consumer not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility (last visited Feb. 22, 2022).

24. Plaintiff and her minor child incurred and will continue to incur medical expenses, has suffered and will continue to suffer pain, loss of enjoyment of life, emotional distress, and medical problems in the future as a direct and proximate result of her ingestion of the contaminated infant formula.

CAUSES OF ACTION

COUNT I

Breach of Express Warranty

25. Plaintiff repeats and re-alleges the allegations above as if set forth herein.

26. Plaintiff formed a contract with Defendant at the time Plaintiff purchased the Defendants Products.

27. The terms of the contract include the promises and affirmations of fact made by Defendant on the Products' packaging and through marketing and advertising, as described above.

28. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain and are part of the standardized contract between Plaintiff and Defendant.

29. As set forth above, Defendant purports through its advertising, labeling, marketing, and packaging, to create an express warranty that the Product is safe for its intended use.

30. Plaintiff performed all conditions precedent to Defendant's liability under this contract when they purchased the Products.

31. Defendant breached express warranties about the Products and their qualities because Defendant's Product contained chemicals unsafe for consumption by babies at the time of purchase and the Products do not conform to Defendant's affirmations and promises described above.

32. Plaintiff would not have purchased the Products had they known the true nature of the harmful chemicals in the Product.

33. As a result of Defendant's breach of warranty, Plaintiff and her minor child suffered

and continue to suffer financial damage and injury, and are entitled to all damages, in addition to costs, interest and fees, including attorneys' fees, as allowed by law.

COUNT II

Breach of Implied Warranty

34. Plaintiff repeats and re-alleges the allegations above as if set forth herein.

35. ALI is a merchant and was at all relevant times involved in the manufacturing, distributing, warranting, and/or selling of the Products.

36. The Products are "goods" under the relevant laws, and ALI knew or had reason to know of the specific use for which the Products, as goods, were purchased.

37. ALI entered into agreements with retailers to sell its Products to be used by Plaintiff for personal use.

38. The implied warranty of merchantability included with the sale of each Product means that ALI guaranteed that the Products would be fit for the ordinary purposes for which baby foods are used and sold, and were not otherwise injurious to consumers. The implied warranty of merchantability is part of the basis for the benefit of the bargain between ALI and Plaintiff.

39. ALI breached the implied warranty of merchantability because the Products are not fit for their ordinary purpose of being consumed by babies because the Products result in *Cronobacter sakazakii* and *Salmonella* infections. Therefore, the Products are not fit for their particular purpose of safely being consumed by babies.

40. ALI's warranty expressly applies to the purchaser of the Products, creating privity between ALI and Plaintiff.

41. However, privity is not required because Plaintiff is the intended beneficiaries of ALI's warranties and its sale through retailers. ALI's retailers were not intended to be the ultimate consumers of the Products and have no rights under the warranty agreements. ALI's warranties were designed for and intended to benefit the consumer only, including Plaintiff.

42. ALI has been provided sufficient notice of its breaches of implied warranties

associated with the Products. ALI was put on constructive notice of its breach through its review of consumer complaints and other reports, including the FDA investigation discussed throughout this complaint, and upon information and belief through its own product testing.

43. Had Plaintiff and the consuming public known that the Products were unsafe for baby consumption, they would not have purchased the Products or would have paid less for them.

44. As a direct and proximate result of the foregoing, Plaintiff and her minor child suffered and continue to suffer financial damage and injury, and are entitled to all damages, in addition to costs, interest and fees, including attorneys' fees, as allowed by law.

COUNT III

Fraudulent Concealment

45. Plaintiff repeats and re-alleges the allegations above as if set forth herein.

46. Plaintiff brings this claim against Defendant, on behalf of herself her minor child T.D.

47. Defendant had a duty to disclose material facts to Plaintiff given their relationship as contracting parties and intended user of the Products. Defendant also had a duty to disclose material facts to Plaintiff, namely that it was in fact manufacturing, distributing, and selling harmful products unfit for use by babies, because Defendant had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

48. Defendant possessed knowledge of these material facts at least four months before issuing their first recall. Further, *Cronobacter sakazakii* and *Salmonella* are not unavoidable in the manufacturing of baby foods.

49. During this time, Plaintiff was using the Products without knowing they posed serious threats to their babies.

50. Defendant failed to discharge its duty to disclose these materials facts.

51. In so failing to disclose these material facts to Plaintiff, Defendant intended to hide from Plaintiff that they were purchasing and consuming the Products with harmful defects that was

unfit for human use, and thus acted with scienter and/or an intent to defraud.

52. Plaintiff reasonably relied on Defendant's failure to disclose insofar as they would not have purchased the defective Products manufactured and sold by Defendant had they known they were not safe for consumption by babies.

53. As a direct and proximate cause of Defendant's fraudulent concealment, Plaintiff suffered damages in the amount of monies paid for the defective Products.

54. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT IV

Unjust Enrichment

55. Plaintiff incorporates the allegations set forth in the preceding paragraphs as though set forth fully herein.

56. Plaintiff conferred benefits on Defendant in the form of monies paid to purchase Defendant's defective and worthless Products.

57. Defendant voluntarily accepted and retained this benefit.

58. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for products unfit for human use, it would be unjust and inequitable for Defendant to retain the benefit without paying the value thereof.

59. Defendant received benefits in the form of revenues from purchases of the Products to the detriment of Plaintiff because Plaintiff purchased mislabeled products that were not what they bargained for and were not safe and effective, as claimed.

60. Defendant has been unjustly enriched in retaining the revenues derived from the purchases of the Products by Plaintiff. Retention of those monies under these circumstances is unjust and inequitable because Defendant's labeling of the Products was misleading to consumers, which caused injuries to Plaintiff because she would have not purchased the Products had they known the true facts.

61. Because Defendant's retention of the non-gratuitous benefits conferred on them by Plaintiff is unjust and inequitable, Defendant must pay restitution to Plaintiff its unjust enrichment, as ordered by the Court.

COUNT V

Breach of the Implied Warranty of Merchantability

62. Plaintiff incorporates by reference all preceding allegations as though fully set forth herein.

63. Plaintiff brings this claim against Defendant, on behalf of herself and her minor child.

64. Defendants are merchants engaging in the sale of goods to Plaintiff.

65. There was a sale of goods from Defendants to Plaintiff.

66. As the developer, manufacturer, marketer, distributor, and/or seller of the defective Products Defendants impliedly warranted to Plaintiff that its Products were fit for their intended purpose in that they would be safe for Plaintiff to use as baby food.

67. Contrary to these representations and warranties, the Products were not fit for their ordinary use, and did not conform to Defendants' affirmations of fact and promises as use of the Products was accompanied by the risk of adverse health effects that do not conform to the packaging.

68. Defendants breached the implied warranty in the contract for the sale of the Products by knowingly selling to Plaintiff a product that Defendants knew would expose Plaintiff to significant health risks, thus meaning Defendants knew that the Products were not fit for their intended purpose.

69. Defendants were on notice of this breach, as they were made aware of the adverse health effects accompanying use of their Products.

70. Plaintiff did not receive the goods as bargained for because the goods she received were not merchantable, as they did not conform to the ordinary standards for goods of the same

average grade, quality, and value.

71. Plaintiff is the intended beneficiary of Defendant's implied warranties.

72. The Products were not altered by Plaintiff.

73. Plaintiff used the Products in the ordinary manner in which such devices were intended to be used.

74. The Products were defective when they left the exclusive control of Defendant.

75. The Products were defectively designed and/or manufactured and unfit for their intended purpose, and Plaintiff did not receive the goods that they bargained for.

76. Plaintiff purchased the Products that contained the Defect, which was undiscoverable by them at the time of purchase.

77. As a result of the defect in the Products, Plaintiff has suffered damages including, but not limited to, the cost of the defective device, loss of use of the device and other related damage.

78. Defendants breached the implied warranty of merchantability to the Plaintiff.

79. Thus, Defendants' attempt to limit or disclaim the implied warranties in a manner that would exclude coverage of the Defect is unenforceable and void.

80. Plaintiff has been damaged by Defendants' breach of the implied warranties.

81. Plaintiff and her minor child have suffered damages in an amount to be determined at trial and are entitled to any incidental, consequential, and other damages and other legal and equitable relief, as well as costs and attorneys' fees, available under law.

COUNT VI

Strict Liability – Failure to Warn

82. Plaintiff incorporates by reference all preceding allegations as though fully set forth herein.

83. Defendants had a duty to warn Plaintiff regarding the Defect and the true risks associated with the Products.

84. Defendants were in a superior position to know of the Defect, yet, as outlined above,

chose to do nothing when the defect became known to them.

85. Defendants failed to provide adequate warnings regarding the risks of the Products after knowledge of the Defect was known only to them.

86. Defendants had information regarding the true risks but failed to warn Plaintiff or to strengthen their warnings.

87. Despite their knowledge of the Defect and obligation to unilaterally strengthen the warnings, Defendants instead chose to actively conceal this knowledge from the public.

88. Plaintiff and would not have purchased, chosen, and/or paid for all or part of the Products if they knew of the Defect and the risks of purchasing the Products.

89. This Defect proximately caused Plaintiff's damages.

90. The Plaintiff and her minor child has suffered damages in an amount to be determined at trial and are entitled to any incidental, consequential, and other damages and other legal and equitable relief, as well as costs and attorneys' fees, available under law.

COUNT VII

Strict Liability – Design Defect

91. Plaintiff incorporates by reference all preceding allegations as though fully set forth herein.

92. The design of the Products was defective and unreasonably dangerous.

93. Use of Defendant's Products by Plaintiff caused exposure to and risk of *Cronobacter sakazakii* and *Salmonella* infections.

94. The design of the Products rendered them not reasonably fit, suitable, or safe for their intended purpose.

95. The dangers of the Products outweighed the benefits and rendered the Products unreasonably dangerous.

96. There are other Products and other similar baby formulas that do not cause *Cronobacter sakazakii* and/or *Salmonella* infections, meaning that there were other means of

production available to Defendants.

97. The Products were unreasonably unsafe, and the Products should have had stronger and clearer warnings or should not have been sold in the market.

98. The Products did not perform as an ordinary consumer would expect.

99. Plaintiff and her minor child have suffered damages in an amount to be determined at trial and are entitled to any incidental, consequential, and other damages and other legal and equitable relief, as well as costs and attorneys' fees, available under law.

COUNT VIII

Negligent Failure to Warn

100. Plaintiff incorporates by reference all preceding allegations as though fully set forth herein.

101. Defendant owed Plaintiff a duty of care and to warn of any risks associated with the Products.

102. Defendant knew or should have known of the defect but failed to warn Plaintiff.

103. Defendants' breach of duty caused Plaintiff economic damages and injuries.

104. Plaintiff and her minor child have suffered damages in an amount to be determined at trial and are entitled to any incidental, consequential, and other damages and other legal and equitable relief, as well as costs and attorneys' fees, available under law.

COUNT IX

Negligent Design Defect

105. Plaintiff incorporates by reference all preceding allegations as though fully set forth herein.

106. Defendant owed Plaintiff a duty to design the Products in a reasonable manner.

107. The design of the Products was defective and unreasonably dangerous, causing *Cronobacter sakazakii* and *Salmonella* infections.

108. The design of the Products caused them to be not fit, suitable, or safe for their

intended purpose. The dangers of the Products outweighed the benefits and rendered the products unreasonably dangerous.

109. There are other baby foods that do not cause *Cronobacter sakazakii* and *Salmonella* infections.

110. The risk/benefit profile of the Products was unreasonable, and the Products should have had stronger and clearer warnings or should not have been sold in the market.

111. The Products did not perform as an ordinary consumer would expect.

112. The Defendants' negligent design of the Products was the proximate cause of damages to the Plaintiff.

113. Plaintiff and her minor child have suffered damages in an amount to be determined at trial and are entitled to any incidental, consequential, and other damages and other legal and equitable relief, as well as costs and attorneys' fees, available under law.

COUNT X

Violation of the Magnuson-Moss Act, 15 U.S.C. § 2301

114. Plaintiff incorporates by reference all preceding allegations as though fully set forth herein.

115. The Magnuson-Moss Act contains, in pertinent part, the following definitions:

(1)The term "consumer product" means any tangible personal property which is distributed in commerce and which is normally used for personal, family, or household purposes (including any such property intended to be attached to or installed in any real property without regard to whether it is so attached or installed)

(3)The term "consumer" means a buyer (other than for purposes of resale) of any consumer product, any person to whom such product is transferred during the duration of an implied or written warranty (or service contract) applicable to the product, and any other person who is entitled by the terms of such warranty (or service contract) or under applicable State law to enforce against the warrantor (or service contractor) the obligations of the warranty (or

service contract).

(4) The term "supplier" means any person engaged in the business of making a consumer product directly or indirectly available to consumers.

(5) The term "warrantor" means any supplier or other person who gives or offers to give a written warranty or who is or may be obligated under an implied warranty.

(7) The term "implied warranty" means an implied warranty arising under State law (as modified by sections 2308 and 2304(a) of this title) in connection with the sale by a supplier of a consumer product.

15 U.S.C.A. § 2301.

116. Plaintiff is a "consumers". 15 U.S.C. § 2301(3).

117. Defendant is a "supplier" and "warrantor." 15 U.S.C. § 2301(4) and (5).

118. The Products are consumer products. 15 U.S.C. § 2301(1).

119. This is a claim arising out of state law, per 15 U.S.C. § 2301 (7).

120. Defendant impliedly warranted that the Products would be free of defects at the time of delivery, and the Products carried an implied warranty of merchantability.

121. Defendant breached its warranties by offering for sale and selling the Products that were by design and construction defective and unsafe, thereby subjecting Plaintiff, who purchased the Products, to damages and risks of loss and injury.

122. Defendant has breached and continues to breach its written and implied warranties of safety, thereby damaging Plaintiff when their Products fail to perform as represented due to an undisclosed Defect.

123. As a result of Defendant's continued breach of its warranties, Plaintiff has suffered damages.

124. Plaintiff seeks full compensatory and consequential damages allowable by law, appropriate equitable relief including injunctive relief, a declaratory judgment, a court order enjoining Defendant's wrongful acts and practices, restitution, attorney's fees and costs, and any

other relief to which Plaintiff may be entitled.

COUNT XI

Punitive Damages

125. Plaintiff incorporates by reference all preceding allegations as though fully set forth herein.

126. At all relevant times, Defendant owed Plaintiff a duty to act with due care and regard for Plaintiff's rights, safety and interests, including their property and financial interests.

127. Defendant breached that duty of due care and such breaches constitute outrageous conduct and reckless disregard of the rights, safety and interests, including property and financial interests, of Plaintiff.

128. Defendant's outrageous conduct towards Plaintiff was done with malice or bad motives or reckless indifference to Plaintiff's interests.

129. Accordingly, Defendant is liable for punitive damages to Plaintiff, the exact amount to be proven at trial.

COUNT XII

Negligent Misrepresentation/Omission

130. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

131. Through its labeling and advertising, Defendant made representations to Plaintiff concerning the safety of their Similac, Alimentum, and EleCare Products.

132. Defendant has a duty to provide accurate information to consumers with respect to their Similac, Alimentum, and EleCare Products as detailed above.

133. Additionally, Defendant has a duty to not make false representations with respect to the safety of their Products.

134. Defendant failed to fulfill its duty when it made false representations regarding the quality and safety of the Products as detailed above.

135. Such failures to disclose on the part of Defendant amount to negligent omission and the representations regarding the quality and safety of the product amount to negligent misrepresentation.

136. Plaintiff reasonably relied upon such representations and omissions to their detriment.

137. By reason thereof, Plaintiff has suffered damages in an amount to be proven at trial.

COUNT XIII

Strict Product Liability – Manufacturing Defect

138. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

139. The Defendant's Similac, Alimentum, and EleCare Products contained a manufacturing defect when they left the possession of Defendant. Specifically, the Products differ from Defendant's intended result or from other lots of the same product line because they contain harmful microorganisms, such as Cronobacter sakazakii bacteria and Salmonella.

140. Plaintiff used the Products in a way that was reasonably foreseeable to Defendant.

141. As a result of the defects in the manufacture of the Defendant's Similac, Alimentum, and EleCare Products, Plaintiff suffered damages.

142. Accordingly, Plaintiff suffered damages in an amount to be proven at trial.

COUNT XIII

Negligence *Per Se*

143. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

144. As documented in the FDA Form 483 issued on September 24, 2019, Defendant failed to test a representative sample of an infant formula production aggregate of powered infant formula at the final product stage and before distribution to ensure that the production aggregate met the required microbiological quality standards.

145. As documented in the FDA Form 483 issued on September 24, 2021, Defendant failed to maintain a building used in the manufacture, processing, packing, or holding of infant formula in a clean and sanitary condition.

146. As documented in the FDA Form 483 issued on September 24, 2021, Defendant personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash their hands thoroughly in a hand washing facility at a suitable temperature after their hands may have become soiled or contaminated.

147. As documented in the FDA Form 483 issued on March 18, 2022, Defendant failed to set in place and/or maintain a system of process controls that cover all stages of infant formula processing to ensure the products do not become adulterated due to the presence of microorganisms, including Cronobacter, in the formula or in the processing environment.

148. As documented in the FDA Form 483 issued on March 18, 2022, Defendant further failed to ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated with microorganisms, including Cronobacter and Salmonella.

149. As documented in the FDA Form 483 issued on March 18, 2022, Defendant failed to document any determination as to whether a hazard to health exists due to contamination with microorganisms, including Cronobacter.

150. As documented in the FDA Form 483 issued on March 18, 2022, Defendant's personnel that worked directly with infant formula, its raw materials, packaging, equipment, or utensil contact surfaces failed to wear necessary protective apparel.

151. The conduct set forth herein, including that documented in the FDA Form 483 reports represent Defendant's conduct in violation of the following statutes or regulations that caused Plaintiff's injury, including the risk of infection and infection of life-threatening microorganisms:

a. 21 U.S.C. § 331 - "The following acts and the causing thereof are prohibited: (a) The introduction or delivery . . . of any food . . . that is adulterated or misbranded.

(b) The adulteration or misbranding of any food . . . .(g) The manufacture . . . of any food . . . that is adulterated or misbranded;"[15]

b. 21 CFR § 106.5 (failing to maintain good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of infant formula);[16]

c. 21 CFR § 106.10 (failing to ensure personnel washed hands);

d. 21 CFR § 106.20(a) (failing to maintain building in a clean, sanitary condition);

e. 21 CFR § 106.30(d) (failing to maintain instruments used to measure, regulate, control parameter);

f. 21 CFR § 106.30(e)(5) (failing to monitor the temperature in thermal processing equipment at a frequency as is necessary to maintain temperature control); and

g. 21 CFR § 106.30(g) (failing to install a filter capable of retaining particles 0.5 micrometer or smaller when compressed gas is used at a product filling machine).

152. Under 21 U.S.C. § 350a, an infant formula, including an infant formula powder, shall be deemed to be adulterated if such infant formula does not meet the quality factor requirements prescribed by the Secretary under subsection (b)(1), or (3) the processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures prescribed by the Secretary under subsection (b)(2).

153. The injury caused to Plaintiff by Defendant's conduct, which violated these statutes and regulations, was the type of injury that the statutes and regulations were designed to prevent.

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[15] *See* 21 U.S.C. § 342 (A food shall be deemed to be adulterated (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health . . . or (4) if it has been prepared, packed, or held under insanitary conditions . . . .); and 21 U.S.C. § 343 (A food shall be deemed to be misbranded . . . if (1) its labeling is false or misleading. . .).

[16] *See* 21 CFR 106.5(b) (The failure to comply with any regulation in this subpart in the manufacture, processing, packing, or holding of an infant formula shall render such infant formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)(3)) . . . .)

154. Additionally, Plaintiff was a member of the class of persons these statutes and regulations were intended to protect. Indeed, as set forth in 21 C.F.R. § 106.5, "compliance with these provisions is necessary to ensure that such infant formula … is manufactured in a manner designed to prevent its adulteration."

155. As a result of Defendant's conduct in the manufacture of the Defendant's Similac, Alimentum, and EleCare Products violating the foregoing statutes and regulations, Plaintiff suffered damages in an amount to be proven at trial.

COUNT XIV

Plaintiff's Claim for Damages Incurred on Behalf of her Minor Child, T.D.

156. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

157. Plaintiff T.D. was a minor at all times referenced in this Complaint.

158. As a direct and proximate result of Defendant's acts and/or omissions, Plaintiff T.D. suffered physical injuries.

159. Plaintiff Heather Davis has a derivative claim for damages because her minor child, T.D., has sustained physical injuries due to the Defendant's conduct.

160. As a result, Plaintiff Heather Davis has a legally recognized claim for damages and seeks reimbursement for medical expenses and other expenses incurred because of Plaintiff T.D.'s injuries.

161. As a result of Defendant's conduct in the manufacture of the Defendant's Similac, Alimentum, and EleCare Products violating the foregoing statutes and regulations, Plaintiff suffered damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE Plaintiff, on behalf of herself and her minor child T.D., respectfully requests that the Court:

a. Enter judgment against each Defendant in favor of Plaintiff;

b. Award to Plaintiff damages (and multiple damages as provided by law) in amounts to be determined at trial;

c. Award to Plaintiff their costs of suit, including reasonable attorneys' fees as provided by law;

d. Grant such other further relief as is necessary to correct for effects caused by Defendant's conduct, as the Court deems just.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all claims in this Complaint and of any and all issues in this action so triable as of right.

Dated: this 11 day of October 2022.

Respectfully submitted,

By: */s/ Paul Doolittle*
Paul Doolittle
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